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EXAMINER

FOREMAN, JONATHAN M

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 47, 52, 60 and 63 - 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al.

In regard to claims 47, 52, 60 and 63 – 67, Williams discloses a method and device for determining a presence or absence of tissue oedema (Col. 1, lines 43 - 47) including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 51 – 53), wherein the alternating current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 2, lines 5 – 6); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 2, lines 55 – 56); and an analysis means to process signals from a first and a second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 2, lines 63 – 67; Col. 7, lines 1 - 20). The first and second measurements are of a same anatomical region separated in time. The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 6, lines 44 – 51). The analysis means is at least one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 7, lines 1 – 20). Williams discloses means for recording bioimpedance (Col. 7, lines 1 – 20). However,

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Williams fails to disclose determining if the result is outside an expected range for an unaffected population to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema including comparing a measured bioelectrical impedance value with a reference value of a population unaffected by tissue oedema, and determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema (See Abstract; Claim 4). The claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value from a population unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Williams for the predictable result of judging whether or not oedema is present in the tissue.

3. Claims 58 and 59 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,807,270 to Williams in view of JP 10000185 A to Kubota et al. as applied to claim 47 above, and further in view of U.S. Patent No. 5,505,209 to Reining.

In regard to claims 58 and 59, Williams in view of Kubota et al. fail to disclose establishing a correction factor from a plurality of subjects unaffected by tissue oedema. Reining discloses a bioelectrical impedance measuring method wherein a correction factor is established from a plurality of subjects in a normal population (See Abstract). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method as disclosed by Williams in view of Kubota et al. to include establishing a correction factor from a plurality of

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subjects unaffected by tissue oedema as taught by Reining in order to minimize error in the measurement (See Abstract).

4. Claims 47 – 55 and 60 – 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,788,643 to Feldman in view of JP 10000185 A to Kubota et al.

In regard to claims 47 – 55 and 60 – 67, Feldman discloses a method and device for determining a presence or absence of tissue oedema including a current means for applying an alternating current to at least one anatomical region (Col. 2, lines 16 – 17), wherein the alternating current is a single low frequency greater than 0 kHz, but no greater than 30 kHz (Col. 5, lines 10 – 17); a monitoring means to measure bioelectrical impedance of said at least one anatomical region and produce a signal characteristic of bioimpedance for said at least one anatomical region (Col. 5, lines 33 – 36); and an analysis means to process signals from a first and a second measurement of bioelectrical impedance to obtain a result to thereby provide an indication of a presence or absence of tissue oedema (Col. 6, lines 1 – 26). The first and second measurements are of a same anatomical region separated in time (Col. 6, lines 17 – 26). The first measurement of bioelectrical impedance is of a first anatomical region of the subject and the second measurement of bioelectrical impedance is of a second anatomical region different than the first anatomical region of the same subject. The first anatomical region and the second anatomical region are paired similar anatomical regions and wherein one of the anatomical regions is unaffected by tissue oedema. The first anatomical region and the second anatomical region are dissimilar and wherein one of the anatomical regions is unaffected by tissue oedema. The anatomical regions are limbs or parts of limbs (Col. 3, lines 57 – 60; Col. 4, line 63 – Col. 5, line 9). The single low frequency alternating current is 10kHz (Col. 5, line 14). The current means includes a proximal electrode and a distal electrode in electrical communication with a power source (Col. 4, line 63 – Col. 5, line 9). The analysis means is at least

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one processing means programmed to perform analysis of data in relation to the first and second measurement of bioelectrical impedance (Col. 6, lines 17 – 26). Feldman discloses means for recording bioimpedance (Col. 6, line 7). Feldman discloses comparing a bioelectrical impedance measurement to a baseline impedance value (Col. 6, lines 1 – 26), but fails to disclose the measurement being compared with a value for bioelectrical impedance from a plurality of subjects unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema. Kubota et al. disclose a method and device for determining a presence or absence of tissue oedema including comparing a measured bioelectrical impedance value with a reference value of a population unaffected by tissue oedema, and determining if the result is outside the expected range to provide an indication of a presence or absence of tissue oedema (See Abstract; Claim 4). The claims would have been obvious because a particular known technique was recognized as part of the ordinary capabilities of one skilled in the art. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the technique of comparing a measured bioelectrical impedance value with a value from a population unaffected by tissue oedema to provide an indication of a presence or absence of tissue oedema as taught by Kubota et al. with the method and device of Feldman for the predictable result of judging whether or not oedema is present in the tissue.

Allowable Subject Matter

5. Claims 56 and 57 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 68 and 69 are allowed.

Response to Arguments

6. Applicant's asserts that Feldman fails to disclose the first measurement of bioelectrical impedance being at a first region and the second measurement being at a second region different than the first region and wherein the first and anatomical region and the second anatomical region are paired similar or dissimilar regions. However, the Examiner disagrees. Feldman discloses that any pair of limbs may be used, or multiple pairs can be used (Col. 5, lines 5 - 8). In regard to Kubota et al., it is noted that the claims do not require the measured bioelectrical impedance values to be compared to a bioelectrical impedance value for an unaffected population. The claims only require determining if the result is outside the expected range for an unaffected population. Kubota et al. discloses determining if the result is outside the expected range for an unaffected population (Abstract; claim 4). It is noted that a population does not necessarily require a plurality.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724.

The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736